

APR 18 2002
PATENT & TRADEMARK RECEIVED
U.S. PATENT AND TRADEMARK OFFICE

1644

Docket Number DM-6909-B

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being sent via United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Rosemarie R. Wilk-Orescan, Esq.
Type or print name


Signature

April 10, 2002
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Arner et al.

Art Unit: 1644

Application No: 09/634,287

Examiner: Patrick J. Nolan

Filed: August 9, 2000

For: Aggrecan Degrading Metallo Proteases

RECEIVED

Assistant Commissioner for Patents
Washington, D.C. 20231

APR 19 2002

TECH CENTER 1600/2900

Response to Restriction/Election Requirement

Sir:

In response to the Restriction/Election Requirement, mailed March 20, 2002, having a shortened statutory period for reply set to expire on April 20, 2002, please consider the remarks appearing herein below.

The Examiner has entered a restriction requirement for this case, requiring an election of the invention to be examined. More specifically, the Examiner has required that the case be limited to one of the following inventions as required by 35 U.S.C. §121:

- I. Claims 66-67 and 69-70, drawn to an antibody to SEQ ID NO:2 and methods of detecting SEQ ID NO:2, using said antibody, classified in class 530, subclass 388.26.
- II. Claims 66, 68-70, drawn to an antibody to SEQ ID NO:15, and methods of detecting SEQ ID NO:15, using said antibody classified in class 530, subclass 388.26.

III. Claims 66, 69 and 71-73, drawn to an antibody to the C-terminus of aggrecan, and methods of detecting the C-terminus, using said antibody, classified in class 530, subclass 380.

In response to this restriction requirement, applicants hereby make a provisional election with traverse to prosecute the invention of Group I., claims 66-67 and 69-70. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. However, it is respectfully submitted that the restriction requirement entered by the Examiner should be withdrawn for the reasons discussed below.

The Examiner has entered the restriction requirement in the present case on the ground that the inventions of Group I -III are distinct because they are unique products and methods, have different physiochemical properties, have acquired a separate status in the art and would confer a serious, undue search burden on the Examiner.

The restriction requirement imposed in this case by the Examiner is improper and should be withdrawn. 35 U.S.C. §121/37 C.F.R. §1.141(a) provides that more than one species of an invention may be specifically claimed in different claims in one application, provided the application also includes an allowable claim generic to all the claimed species, and all the claims to species in excess to one are written in dependent form, or otherwise include all the limitations of the generic claim. Claim 66 of the present application is a generic claim to an antibody to an Aggrecan Degrading Metallo Protease (ADMP). ADMPs are defined in the specification on page 8, last paragraph, as a family of polypeptides that are capable of cleaving the aggrecan core protein at the GLU³⁷³-ALA³⁷⁴ peptide bond, but do not readily cleave at the ASN³⁴¹-PHE³⁴² peptide bond and consist of the following domains: a propeptide domain containing a furin site, followed by a metalloprotease domain, followed by a desintegrin-like domain, followed by a thrombosponden homologous domain, wherein the polypeptide is either a native or recombinant peptide. The specification further defines ADMPs as including sequences 80% homologous to SEQ ID Nos: 2 and 15, retaining the desired biological activity. The term "neoepitope antibody" (defined on age 7, line 1 of the specification) means an

antibody which specifically recognizes a new N-terminal amino acid sequence or new C-terminal amino acid sequence generated by proteolytic cleavage but does not recognize these same sequences of amino acids when they are present within the intact protein. The neoepitope antibody of the present invention is limited by the parameters of claim 66, specifically that they must recognize the newly-formed C terminus of the globular domain of aggrecan following proteolytic cleavage by the ADMP. Applicants submit that antibodies to SEQ ID Nos: 2 ,15 and to the C-terminal globular domain neoepitope are representative species of the genus described in the specification and referred to in claim 66 and should therefore be examined on the merits together in one application. Applicants further assert that a search of the three representative sequences would not impart a serious, undue search burden on the Examiner

Applicants respectfully request the withdrawal of the restriction requirement.

Respectfully submitted,



Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000

Rosemarie R. Wilk-Orescan, Esq.
Attorney for Applicants
Reg. No. 45,220
Phone No. 609-252-3575

Date: 10 April 2002